I hereby certify that this correspondence is being sent by facsimile transmission to Corrine McDermott, on the date shown below.

Dated: July 7, 2003 Signature: (Monica L. Thomas)

Docket No.: HO-P01952US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Julie A. Bearcroft, et al.

Application No.: 09/517,981 Group Art Unit: 3738

Filed: March 3, 2000 Examiner: B. Pellegrino

For: SHAPED PARTICLE AND COMPOSITION FOR BONE DEFICIENCY AND METHOD OF MAKING THE PARTICLE

DECLARATION UNDER 37 CFR §1.132

Dear Sir:

I, Michael B. Cooper, do hereby depose and say as follows:

1. I am a United States citizen residing at 5665 Dunwoody Ave., TN, USA.
2. I am an employee of the assignee of the above-referenced patent application, I am an inventor of said application, and I have read the contents of said application.
3. I am a Manager of Research Projects at Smith + Nephew, Inc. I am skilled in the area of bone substitute methods and compositions. A resume describing my experience is attached to this declaration.

Claims 2, 3, 5-8 10-16, 22, 65, 68, 71-74, and 78 remain rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,676,700 ("Black") alone and in combination with other references.

The present invention is not obvious in view of Black for multiple reasons. Black teaches away from the present invention, and, furthermore, any argument that Applicants' circular cross-section is an obvious matter of design choice in light of Black's oval cross-section is inaccurate.

The shaped particles of the present invention are designed to reflect both interlocking of adjacent particles and the porosity useful for a bone treatment, specifically for ingrowth of bone (such porosity is implicit and well-known to be desirable in a shaped bone graft substitute such as the inventors'). It is not obvious which cross-sectional shape or shapes would impart <u>both</u> of such advantages, and an infinite number of cross-sectional shapes could

be tested in determining one that is useful for both interlocking and porosity (note the Sheppard reference even utilizes a square cross-section, although it likely provides insufficient porosity for bone ingrowth). Particularly regarding cross-sections related to circles and ovals, there is nothing obvious or intuitive that an oval cross-section as a design for an interlocking particle that also allows porosity would indicate a circular cross-section would perform similarly.

Not only is there <u>not</u> an obvious matter of cross-sectional design choice to select a circle in view of an oval, but a skilled artisan from reading Black would likely refrain from considering a circular cross-section design, given that the reference refers to advantages of having an oval cross-sectional configuration (col. 3, lines 33-38). Because of this teaching, a skilled artisan in this field would not necessarily presume a circular cross-section would have the same advantage and, furthermore, would likely avoid the labor and expense to perfect its design and manufacture, given the acknowledged advantage of the oval cross-section.

Black states (col. 3, lines 23-42):

> The tightly meshed array 42 of interlocked structural elements 10 establishes a structural matrix of sound mechanical cohesive characteristics for attaining desirable mechanical properties, while providing an osteoconductive or osteoinductive matrix for the ingrowth of natural bone. Thus, the interengaged structural elements 10 are meshed tightly enough and are interlocked to provide a structural matrix which tends to resist shear stress in essentially all directions within the array 42, while the nature of the material of the structural elements 10 allows for the ingrowth of natural bone. The oval cross-sectional configuration of the posts 12, and the tapering of the posts 12 along the length L thereof, enhance the ability of the posts 12 to enter the inter-post spaces 16 and attain meshing and interlocking of the structural elements 10 in the desired tight relationship. The mechanical strength of the matrix thus provided by the array 42 is sufficient to enable load-bearing, even upon initial implant of the femoral implant 32, whether utilized alone to fill a void such as cavity 30, or in combination with autologous bone or autologous blood.

Thus, Black teaches that its particles have similar advantages to those demonstrated by our particles. If a skilled artisan is taught by Black that a particle with an oval cross-section has the advantage of providing both porosity and an interlocking shape, then why would a skilled artisan presume the same would be provided by a shape <u>lacking</u> the contour of an oval (*e.g.*

not having two longer "sides" of its contour), particularly when Black asserts: "[the] oval cross-sectional configuration of the posts…enhance[s] the ability of the posts…to enter the inter-post spaces…and attain meshing and interlocking"?

An oval, in the context of the present invention, is not necessarily similar *in function* to a circle. An oval shape in particular would not intuitively teach similar advantages for a circular cross-section. For example, the longer "side" of the oval contour can lie flat against the longer side of the oval contour of an adjacent particle for one pair of adjacent particles in an array, whereas the longer side of the oval contour of one particle can lie against the shorter "side" for another pair of adjacent particles in the same array. This configuration would thereby impart a somewhat unpredictable porosity for an array that is not palpable in function with an array from particles having circular cross-sections.

As stated, bone graft substitutes are used in the art as bone void fillers to preferably provide an environment having consistent porosity and interlocking for any void, void volume, or shape of void. It is extremely important to recognize that it is not intuitive what geometry would provide such an environment. It is not necessarily true that the configuration of particles having oval cross-sections would provide consistent interlocking and porosity, and in the case of oval cross-sections it is unclear that the dissimilar contours for the "sides" of the oval would provide consistency. It is simply not obvious what shapes would meet these conditions, including whether circular cross-sections would be satisfactory.

The circular cross-section of the extremities of the particle are certainly not an obvious matter of design choice. The design choice of the circular cross-section compared to the oval should not function in the same manner for their intended purpose, given their dissimilar contours. The circular cross-sectional area has proportionately the same forces in any direction across the cross-section, whereas in an oval cross-section the forces are not. For example, the forces across the different amounts of material (depending on the direction) of the cross-section in the oval-based arm provides weaker points in terms of tensile strength and so forth. The inherent functional differences mean that the design of the oval is not interchangeable with the design of the circle. The substitution of a circle for an oval cross-section is not a trivial substitution, and in the design of the particles of the present invention we have discovered that the circular cross-sectional properties are critical to how it functions. It would not be a mere design choice to exchange circle for oval.

Thus, I hereby state that in view of the above discussion the design of the particle of the Black reference does not render our particle obvious and, furthermore, that in teaching away from our invention our particle can not be obvious in view of Black.

4. I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 7-1-03

Michael B. Cooper

MICHAEL BRIAN COOPER

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EXPERIENCE

September 1993 - Present — **SMITH & NEPHEW INC.**, Memphis, TN

August 2001- Present — **Manager Research Projects II – Smith & Nephew Inc.**
July 1999- August 2001 — **Manager Research Projects – Smith & Nephew Inc.**
July 1997 – July 1999 — **Senior Research Engineer - Smith & Nephew Inc.**
September 1993 - June 1997 — **Research Engineer II - Smith & Nephew Inc.**

- Managed technical programs comprised of multidisciplined individuals
- Developed business strategy and performed customer research to define market share for new product ideas
- Developed and managed budgets for technical programs
- Supervised department of research engineers
- Managed the development and introduction of Smith & Nephew's first antimicrobial coating and bone graft substitute products
- Introduced and managed the implementation of injection molding and polymer machining technology programs that resulted in a $600,000 per year cost reduction for Smith & Nephew product lines
- Managed technical program that reduced the rejection rates on polymer products from 40% to approximately 1%

May 1991 – May 1993 — **Japanese Automobile Manufacturers Association in affiliation with The University of Tennessee Engineering Institute for Trauma and Injury Prevention,** Knoxville, TN

Research Engineer

- Developed, performed, and analyzed vehicle-human impact interaction through experimental and finite element analysis methods
- Designed experimental testing apparatus to measure tibial fracture propagation during high speed impact

EDUCATION

Masters of Science, Engineering Science and Mechanics, May 1993
University of Tennessee Knoxville, TN

Master's Thesis: "A Three-Dimensional, Nonlinear, Transient Dynamic, Finite Element Analysis of the Embalmed Human Tibia Subjected to High Speed Impact Loading"

Bachelor of Science, Engineering Science and Mechanics, May 1991,
Specializing in solid mechanics and biomechanics
University of Tennessee, Knoxville, TN

PUBLICATIONS & PATENTS Available upon request